510(k) Summary

1. Submitter Identification

510(k) Submitter	GRANDWAY TECHNOLOGY (SHENZ
Address	Block 6 and 7, Zhu Keng Industrial Zon District, Shenzhen, Guang Dong, People's
Phone Number	(00852)-2851-6789
Fax Number	(00852)-2851-6278
Contact Person	Mr. Patrick Chow
Date of Submission	19th November, 2013

2. Device Identification

Trade Name	Digital Automatic Wrist Blood Pr Series [Model No.: MD22xy] **x** --- The first character (2 & 3) cabinet (housing). **y** --- The second character (0, 1 change revision of device. The n refers to those device changes conformity test results of EMC & performance, i.e. IEC60601-1 and
Common Name	Non-invasive Blood Pressure Mea

4. Device Description

Digital Automatic Wrist Blood Pressure Monitor WBPM22 Serie
pressure measurement system for use by medical professional or
measure the systolic and diastolic blood pressure, and pulse rate
measurement and then display the readings on a digital panel.

The device utilizes the oscillometric methodology, in which an i
around the Wrist of an individual, for blood pressure measuremen
detects your blood's movement through your brachial artery and co
a digital reading.

The table below illustrate the feature presence in Digital Autom
Monitor WBPM22 Series.

Model	Blood Pressure Measurement	Pulse Rate Measurement	WHO Classification	Irregular Heartbeat
MD2220	✔	✔	✔	✔
MD2222	✔	✔	✔	✔
MD2223	✔	✔	✔	✔
MD2230	✔	✔	✔	✔
MD2231	✔	✔	✔	✔
MD2232	✔	✔	✔	✔

5. Indication for Use

6. Comparison of Technological Characteristics betwe Predicate Devices

Digital Automatic Wrist Blood Pressure Monitor WBPM22 Se predicate device, WBPM15 Series (K120673) in the device compar

Comparison between WBPM22 Series and predicate de		
Item	**Predicate Device**	**WBPM22 S**
Indication for Use	Digital Automatic Wrist Blood Pressure Monitor WBPM15 Series is for use by medical professional or at home. The WBPM15 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate (heartbeat rate) of an individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the wrist of an individual. The inflatable cuff circumference is limited to 13.5cm - 19.5cm.	Digital Automatic Wris Monitor WBPM22 Seri medical professional or WBPM22 Series is inte the systolic and diastoli and pulse rate of an ad using a non-invasive tec an inflatable cuff is wr wrist.
Measurement Method	Non-invasive, Oscillometric	Non-invasive, Oscillome
Irregular Heartbeat Detection (IHB)	Yes	Yes
Patient Population	Age 16 or above	Age 16 or above
Blood Pressure Measurement Range	Cuff Pressure: 0 - 300 mmHg Systolic Pressure: 50 - 250 mmHg Diastolic Pressure: 30 - 200 mmHg	Cuff Pressure: 0 - 300 m Systolic Pressure: 50 - 2 Diastolic Pressure: 30 - 2
Number of User	2 independent users	2 independent users
Memory Space	2 users × 120 memory space	2 users × 60 memory spa 2 users × 120 memory sp
Blood Pressure Measurement Accuracy	± 3 mmHg or 2% of reading	± 3 mmHg or 2% of read
Pulse Rate	30 - 180 beats/min	30 - 180 beats/min

Comparison between WBPM22 Series and predicate device			
Item	**Predicate Device**	**WBPM22 Series**	**Comment**
Storage and Transportation Condition	Temperature: -20 - 60 °C Humidity: 10 - 95 % R.H. max Atmospheric Pressure: 700 - 1060 kPa	Temperature: -20 - 60 °C Humidity: 10 - 95 % R.H. max Atmospheric Pressure: 700 - 1060 kPa	Identical
Material	Resistances, capacitance, transistors, amplifiers, pressure sensor, CPU, PCB, cuff ABS button, ABS cabinet, batteries and packaging	Resistances, capacitance, transistors, amplifiers, pressure sensor, CPU, PCB, cuff ABS button, ABS cabinet, batteries and packaging	Identical
Compatibility with Environment and Other Devices	No influence with environment and other device	No influence with environment and other device	Identical
Applicable Standard	✧ EN 1060-1:1995/A2:2009 ✧ EN 1060-3:1997/A2:2009 ✧ IEC 60601-1:2005+ CORR.1(2006)+CORR. 2 (2007) ✧ EN 60601-1-2:2007 ✧ FCC Part 15 ✧ ISO 10993-5:2009 ✧ ISO 10993-10:2002 + A1:2006 ✧ EN 60601-1-4:2007 ✧ ANSI/AAMI SP-10:2002	✧ EN 1060-1:1995+A2:2009 ✧ EN 1060-3:1997+A2:2009 ✧ IEC 60601-1:2012 ✧ EN 60601-1-2:2007 ✧ FCC Part 15 Subpart B ✧ ISO 10993-5:2009 ✧ ISO 10993-10:2010 ✧ IEC 62304:2006 ✧ IEC 81060-2:2009	Equivalent, change upon FDA's recognized standard

Digital Automatic Wrist Blood Pressure Monitor WBPM22 Series is a non-invasive measuring device and utilizes the oscillometric methodology to measure the blood pressure reading. The key components of device are: a pressure sensor, a electric valve and an electronic control module together with an electric pump. The electric pump inflate (and deflate) the inflatable cuff automatically according to our designed architecture. The predicate device adopts exactly same methodology and key components for measuring blood pressure.

7. Clinical and Non-clinical Tests

Clinical Test Summary

Testing to insure clinical accuracy of the device in accordance with ISO 81060-2:2009 as documented in Clinical Test report.

One hundred patients (49 males and 51 females) were invited for the study. Standard auscultation method was used as the reference blood pressure monitor measuring in the left wrist. Blood pressure measurements were repeated alternatively with the device and auscultation in the same arm according to the sequence in ISO 81060-2:2009.

Non-Clinical Test Summary

Digital Automatic Wrist Blood Pressure Monitor WBPM22 Seri
non-clinical tests to show that all requirement specifications and
met. The tests includes the follows:

- ✧ EN 1060-1:1995+A2:2009
- ✧ EN 1060-3:1997+A2:2009
- ✧ IEC 60601-1:2012
- ✧ EN 60601-1-2:2007
- ✧ FCC Part 15 Subpart B
- ✧ ISO 10993-5:2009
- ✧ ISO 10993-10:2010
- ✧ IEC 62304:2006

As all of the clinical and non-clinical testing performed on Digit
Pressure Monitor WBPM22 Series are same as the predicate devic
is conducted to show the performance of Digital Automatic Wris
WBPM22 Series is equivalent to the predicate device.

8. Conclusion

Digital Automatic Wrist Blood Pressure Monitor WBPM22 Series
and same technological characteristics as the predicate device, Digi
Pressure Monitor WBPM15 Series (K120673). Moreover both
testing has demonstrated that no differences in the technol
questioning on safety or effectiveness to be raised. Thus, Digita
Pressure Monitor WBPM22 Series is substantially equivalent to the

DEPARTMENT OF HEALTH & HUMAN SERVICES

March 5, 2014

Grandway Technology (Shenzhen) Limited
Patrick Chow
Zhu Keng Industrial Zone
Ping Shan, Long Gang District
Shenshen, Guang Dong, 518118 CH

Re: K133618
Trade/Device Name: Digital Automatic Wrist Blood Pressure M
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement S
Regulatory Class: Class II
Product Code: DXN
Dated: February 12, 2014
Received: November 25, 2013

Dear Patrick Chow,

We have reviewed your Section 510(k) premarket notification of intent t
referenced above and have determined the device is substantially equival
for use stated in the enclosure) to legally marketed predicate devices mar
commerce prior to May 28, 1976, the enactment date of the Medical Dev

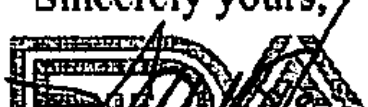
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In a
publish further announcements concerning your device in the Federal Reg

Please be advised that FDA's issuance of a substantial equivalence determ
that FDA has made a determination that your device complies with other
or any Federal statutes and regulations administered by other Federal age
with all the Act's requirements, including, but not limited to: registration
Part 807); labeling (21 CFR Part 801); medical device reporting (reportin
related adverse events) (21 CFR 803); good manufacturing practice requi
the quality systems (QS) regulation (21 CFR Part 820); and if applicable,
radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-

If you desire specific advice for your device on our labeling regulation (2
contact the Division of Small Manufacturers, International and Consume
free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.h
Also, please note the regulation entitled, "Misbranding by reference to pr
(21 CFR Part 807.97). For questions regarding the reporting of adverse e
regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm
for the CDRH's Office of Surveillance and Biometrics/Division of Postm

You may obtain other general information on your responsibilities under
Division of Small Manufacturers, International and Consumer Assistanc
(800) 638 2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.h

Sincerely yours,



Section 5 Indication for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Digital Automatic Wrist Blood Pressure Monitor WBPM22 Series

Indications for Use *(Describe)*
Digital Automatic Wrist Blood Pressure Monitor WBPM22 Series is for use by medical professional or home user. The WBPM22 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the wrist.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Date: 2014.03.05
16:08:17 -05'00'
for Bram Zuckerman

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